Docket No. 64688/152

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

GENE TRANSFER INTO RENAL GLOMERULAR CELLS

the specification of which (check one)

is attached hereto

X was filed on ***10/10/2001*** as Application Serial No. **09/972,956** and was amended on_____ (if applicable).

This application takes priority under 35 USC 120 from US Serial No. **60/246,041, filed 11/02/2000**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in Title 37, Code of Federal Regulations 1.56.

I hereby appoint as my attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: **Dr. Melvin Blecher, Reg. No. 33,649.**

Send all correspondence to **4329 Van Ness St., NW, Washington, DC 20016-5625.** Address telephone communications to *Dr. Melvin Blecher at Tel. (202)-363-3338; FAX (202) 362-8404*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor
Xuehai Ye, PhD

Signature of First or Sole Inventor

Date January 13, 2003

Residence Address

9623 Scotch Haven Drive

Country of Citizenship *United States of America*

Post Office Address
Vienna, VA 22161 (USA)

Full Name of Second Inventor
Patricio E. Ray, MD

Signature of Second Inventor

Date

Residence Address
8505 Fox Run

Country of Citizenship *Argentina (perm. U.S.A. resident)*

Post Office Address
Potomac, MD 20854 **(USA)**

Docket No. 64688-182

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

GENE TRANSFER INTO RENAL GLOMERULAR CELLS

the specification of which (check one)

is attached hereto

X was filed on *10/10/2001* as Application Serial No. 09/972,956 and was amended on_____ (if applicable)

This application takes priority under 35 USC 120 from US Serial No. 60/246,041, filed 11/02/2000

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in Title 37, Code of Federal Regulations § 1.56.

I hereby appoint as my attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Dr. Melvin Blecher, Reg. No. 33,649.

Send all correspondence to 4329 Van Ness St., NW, Washington, DC 20016-5625. Address telephone communications to *Dr. Melvin Blecher at Tel. (202) 363-1355, Fax (202) 362-8424.*

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor	Signature of First or Sole Inventor	Date
Xuehai Ye, PhD		
Residence Address 9623 Scotch Haven Drive		Country of Citizenship *United States of America*
Post Office Address Vienna, VA 22161 (USA)		

Full Name of Second Inventor	Signature of Second Inventor	Date
Patricia E. Ray, MD		1/22/03
Residence Address 8505 Fox Run		Country of Citizenship *United States of America*
Post Office Address *Potomac, MD 20854* (USA)		

1/7/9
DIALOG(R)File 55:Biosis Previews(R)

12879399 BIOSIS NO.: 200100086548
Efficient gene transfer to rat renal glomeruli with recombinant adenoviral vectors.
AUTHOR: Ye Xuehai (a); Liu Xue-Hui; Li Zhuangwu; Ray Patricio E
AUTHOR ADDRESS: (a)Children's National Medical Center, Children's Research Institute, 111 Michigan Avenue, N.W., Rm. R180, 3.5R, Washington, DC, 20010: xye@cnmc.org**USA
JOURNAL: Human Gene Therapy 12 (2):p141-148 January 20, 2001
MEDIUM: print
ISSN: 1043-0342
DOCUMENT TYPE: Article
RECORD TYPE: Abstract
LANGUAGE: English
SUMMARY LANGUAGE: English

ABSTRACT: Recombinant adenoviruses are attractive vectors for renal gene transfer since they can efficiently transduce nondividing cells. However, despite the fact that renal glomeruli are easily accessible via the renal circulation, attempts to deliver foreign genes specifically into renal glomeruli, using adenoviral vectors, have had limited success in rodents. A simple intraarterial injection of adenoviral vectors into the renal circulation or incubation of the virus with the kidney for an extended period of time was found to be insufficient for this purpose. In this study, we have established an efficient gene transfer protocol to express foreign genes in rat renal glomerular cells, using adenoviral vectors. We demonstrated, for the first time, that rat glomerular endothelial cells could be efficiently transduced by slowly infusing a recombinant adenovirus (Ad.CBlacZ) into the right renal artery for a period of 15 min. High levels of lacZ expression were achieved in renal glomeruli without causing significant damage to renal glomeruli or other kidney structures. The virus-mediated expression lasted for at least 21 days. These data demonstrate the feasibility of using recombinant adenoviral vectors as a tool with which to study the effect of foreign gene expression on the structure and function of rat renal glomeruli in vivo.
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DIALOG(R)File 55:Biosis Previews(R)

13084436 BIOSIS NO.: 200100291585
Efficient gene transfer to rat renal glomeruli with recombinant adenoviral vectors.
AUTHOR: Ye Xuehai (a); Liu Xue-Hui; Li Zuangwu; Ray Patricio E
AUTHOR ADDRESS: (a)Center for Genetic Medicine, Children's Research Institute, Children's National Medical Center, Washington, DC**USA
JOURNAL: Pediatric Research 49 (4 Part 2):p421A April, 2001
MEDIUM: print
CONFERENCE/MEETING: Annual Meeting of the Pediatric Academic Societies Baltimore, Maryland, USA April 28-May 01, 2001
ISSN: 0031-3998
RECORD TYPE: Citation

LANGUAGE: English
SUMMARY LANGUAGE: English
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Attorney Dkt. No. 64688/152

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re; application of:
Xuehai Ye et al
Serial No. 09/972,956
Filed 10/10/2002
Priority date 11/06/2000
For: Gene Transfer Into Renal Glomerular Cells

GAU 1614
Examiner J. E. Angell

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
Box Non-fee Amendment
Washington, DC 20231

Sir:

I, Mark L. Batshaw, MD, declare that:

I reside at 3315 Highland Place, Washington, DC.

I am the Chief Academic Officer and Director of the Children's Research Institute of the Childrens National Medical Center, Washington, DC.

I am also Professor and Chairman of the Department of Pediatrics of the George Washington University School of Medicine.

I am a pediatrician and researcher, with both activities being centered on gene-based cases of mental retardation and other developmental disabilities in children.

I have had a long collaboration with James Wilson, MD, PhD, former Director of the Institute of Human Gene Therapy at the University of Pennsylvania Medical Center.

Under this collaboration, I have concentrated on developing methods to cure genetic errors in metabolism in children. Included in this research were attempts to develop animal models of human genetic diseases, in particular in attempting to cure ornithine transcarbamylase deficiency (OTCD) in the sparse fur mouse by administering to these mice a virus vector carrying the OTC gene. We developed a means of injecting the vector without having the body marshal its immune mechanism to destroy the virus. Substantial improvements in the medical condition of one of these animals were observed. These results have been described (Batshaw ML, Yudkoff, M, McLaughlin BA, Gorry E, Anegawa NJ, Smith, I, Hyman, SL, Robinson MB. The sparse fur mouse as a model for gene therapy in ornithine carbamoyltransferase deficiency. Gene Therapy 1995; 2:743-749; Ye X, Robinson MB, Batshaw ML, Furth EE, Smith I, Wilson JM. Prolonged metabolic correction in adult ornithine transcarbamylase-deficient mice with adenoviral vectors. J Biol Chem 1996; 271:3639-3646; Ye X, Robinson MB, Pabin C, Quinn T, Jawad A, Wilson JM, Batshaw ML. Adenovirus-mediated in vivo gene transfer rapidly protects ornithine transcarbamylase deficient mice from an ammonium challenge. Pediatric Res, 1997; 41:527-534.

From these experiences I and others in the field became convinced that a major research thrust should be to develop animal models of gene-linked diseases, and many such efforts became successful in the late 1990s and early 2000s.

I am familiar with the details of the captioned patent application that describes a surgically-created animal model to test candidate gene vectors for their ability to be transferred into renal glomerular cells.

In my expert opinion, the invention described in Drs. Ye and Ray's patent application would have been recognized by one of average skills in this art to have specific, substantive and credible usefulness at the time (year 2000) their patent application was filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted.

Date: 1/22/03

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Home Address	3315 Highland Place, Northwest Washington, D.C. 20008 (202)966-5934 Fax: (202)966-5935 Social Security No: 151-34-7708 DOB: September 19, 1945

Education		
	1963-67	B.A. University of Pennsylvania (cum laude, Honors, Natural Science)
	1967-71	M.D. University of Chicago, Pritzker School of Medicine

Postgraduate Training and Fellowship Appointments		
	1971-73	Residency in Pediatrics, Hospital for Sick Children, University of Toronto, Canada
	1973-75	Fellowship, Developmental Pediatrics, Kennedy Institute, Johns Hopkins University School of Medicine, Baltimore, Md.

Faculty Appointments		
	1975-76	Instructor, Department of Pediatrics, Johns Hopkins University School of Medicine
	1976-80	Assistant Professor, Dept. Pediatrics, Johns Hopkins University School of Medicine
	1980-88	Associate Professor, Dept. Pediatrics, Johns Hopkins University School of Medicine
	1988-90	Professor of Pediatrics, University of Pennsylvania School of Medicine
	1989-98	Professor of Neurology, University of Pennsylvania School of Medicine
	1990- 98	W.T. Grant Professor of Pediatrics, University of Pennsylvania School of Medicine
	1995-98	Professor of Rehabilitation Medicine, University of Pennsylvania School of Medicine
	1998-	Adjunct Professor of Pediatrics, University of Pennsylvania School of Medicine
	1998-	"Fight for Children" Chair of Academic Medicine, Professor and Chair, Department of Pediatrics, The George Washington University School of Medicine and Health Sciences
	2001-	Associate Dean for Academic Affairs, The George Washington University School of Medicine and Health Sciences

Hospital and Administrative Appointments		
	1975-88	Developmental Pediatrician, Director of Metabolism Research, Kennedy Institute, Baltimore
	1988-98	Physician-in-Chief, Children's Seashore House, Philadelphia; Chief, Division of Child Development and Rehabilitation Medicine, The Children's Hospital of Philadelphia
	1990-98	Founding Director, Mental Retardation Research Center, Children's Seashore House, The Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine

	1990-93	Committee on Appointments and Promotions, University of Pennsylvania School of Medicine (Chairman, 1991-93)
	1992-98	Director, University Affiliated Program in Developmental Disabilities (Children's Seashore House and University of Pennsylvania School of Medicine)
	1996-99	Co-Chair, Executive Committee, Institute for Human Gene Therapy, University of Pennsylvania School of Medicine
	1996-99	Member, Graduate Group in Cell and Molecular Biology, University of Pennsylvania School of Medicine
	1998-	Chief Academic Officer, Children's National Medical Center, Washington, DC
	1998-	Director, Children's Research Institute, Children's National Medical Center
	2001-	Founding Director, Mental Retardation and Developmental Disabilities Research Center, Children's National Medical Center
Specialty Certification	1975	Fellow Royal College of Physicians (Canada)- Pediatrics
	1976	American Board of Pediatrics
	2001	Neurodevelopmental Pediatrics (newly established board)
Licensure	Maryland and Washington, D.C.	
Awards, Honors and Memberships in Honorary Societies	1980-	Society for Pediatric Research
	1982-	Alexander Schaffer Award for Excellence in Clinical Teaching, Johns Hopkins University School of Medicine
	1983-1986	Joseph P. Kennedy, Jr. Scholar
	1988-1998	John Morgan Society, University of Pennsylvania; President 1993
	1989-	American Pediatric Society
	1989-1995	College of Physicians & Surgeons, Philadelphia
	1989-	American Pediatric Society
Memberships in Professional and Scientific Societies	American Academy of Pediatrics Society for Inherited Metabolic Disorders, (President, 1995-1996) Society for Developmental Pediatrics, Board of Directors, 1992-2002 Mental Retardation Research Centers, 1990- (President 1994-97) Society for Pediatric Research American Association of University Affiliated Programs American Association on Mental Retardation American Society of Gene Therapy	
NIH Study Section	1991-95: Mental Retardation Research Committee, National Institute of Child Health and Human Development (NICHD)	

Legislation	1994-1997: Annual report to Congress on the accomplishments of the Mental Retardation and Developmental Disabilities Research Centers 3/31/95: Testimony before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, United States Senate 3/6/02: Testimony before the Presidents Commission on Special Education, Denver, CO.
Editorial Positions	1994-2001: Founding Editor-in-Chief, Mental Retardation and Developmental Disabilities Research Review
Consultant Position	1992-1995: National Board of Medical Examiners, Consultant on accommodation for disabilities
Academic Committees	Intern Selection Committee, Dept. Pediatrics, Johns Hopkins (1977-81) Medical School Council (Faculty Senate), Johns Hopkins University School of Medicine-1982-86 (Chairman, 1985-86) Joint Committee on Housestaff and Fellowship Training, Johns Hopkins (1983-86) Ad hoc Committee on Fellowship Training, Dept. of Pediatrics, PENN, Chairman, (1989) Executive Committee, Fellowship Training Program, Children's Hospital of Philadelphia (1990) Medical School Advisory Committee, Children's Hospital of Philadelphia (1990-1998) Search Committee for the Chief of the Division of Hematology, University of Pennsylvania School of Medicine - CHOP, Chairman (1990-91) Division Chiefs' Research Committee, CHOP (1990-1998) Search Committee for Chairman of Rehabilitation Medicine, PENN, Chairman (1995-96) Faculty Grievance Commission, Hearings List (9/96-6/30/99)
Patent	Brusilow S.W., Batshaw M.L. and Radin N.S.: Process for waste nitrogen removal. #4,284,647, 8/14/81
Major Teaching and Clinical Responsibilities	• Practice of Medicine (interviewing and physical diagnosis) Year 1 and 2. • Developmental Disabilities Clinic, 1 session/week • Metabolism clinic, 1 session/week
Trainee History	Dr. Batshaw has been a mentor to over 20 junior faculty and post-doctoral fellows. A table summarizing accomplishments of trainees is appended.
External Grant Support	ONGOING: 1P30HD40677-01 (P.I. Mark L. Batshaw) 8/1/01-7/31/06 NIH, NICHD $572,934 (total direct costs) Mental Retardation and Developmental Disability Research Center at Children's National Medical Center. The main goal of this project is the operation of a center of excellence for research and training in the area of mental retardation and developmental disabilities in Washington, D.C. 1P30HD40677-01 (P.I. Mark L. Batshaw) 10/1/02-9/30/03

NIH, NICHD $50,000
MRDDRC at Children's National Medical Center: Administrative supplement for Center for Rare Diseases Planning Grant

1K12HD01399 (P.I. Mark L. Batshaw) 12/1/00-11/30/05
NIH, NICHD $400,000
Child Health Research Career Development Award.

The major goal of this project is to support the career development of pediatricians beginning careers in basic/translational research relevant to child health.

1G20RR15248-01A2 (P.I. Mark L. Batshaw) 4/1/02-3/31/03
NIH, NCRR $581,751
Developing and Improving Institutional Animal Resources.

The major goal of this project is to upgrade and renovate the research animal facility at CNMC.

009424 (Mark L. Batshaw) 7/1/01-6/30/03
THE KETTERING FAMILY FNDN $300,000
Ornithine Transcarbamylase Deficiency Research.

The major goal of this project is to further our understanding of OTC deficiency and develop gene therapies to correct it.

COMPLETED:

1C06RR14515-01 (P.I. Mark L. Batshaw) 9/30/99-9/29/02
NIH, DRR $980,000
Extramural Research Facilities Construction.

The major goal of this project is to complete the buildout of 11,268 square feet of space to house the Molecular Genetics Center for Pediatric Diseases.

O'MALLEY FOUNDATION (P.I. Mark L. Batshaw) 7/1/97-6/30/00
Ornithine Transcarbamylase Deficiency. $300,000

The major goal of this project was to explore novel approaches to gene therapy in children with inborn errors of metabolism.

5P01 HD32649-05 (P.I. Mark L. Batshaw) 12/15/94-11/30/00
NIH, NICHD $874,813
Gene Therapy for Ornithine Transcarbamylase Deficiency.

The major goal of this project was to explore novel approaches to gene therapy in children with inborn errors of metabolism.

5P30HD026979
NIH, NICHD (P.I. Mark L. Batshaw) 8/1/90-7/1/98
Mental Retardation Research Center-Children's Hospital of Philadelphia

The goal of this center was to study causes and treatment of developmental disabilities

5RO1NS028033
NIH, NINDS (P.I. Mark L. Batshaw) 3/1/86-4/31/93
Neurotransmitters, appetite and inborn errors of metabolism

The aim of this study was to understand the neurotransmitter abnormalities underlying neurologic abnormalities in inborn errors of urea synthesis using animal models and human studies

5P01HD010981
NIH, NICHD (P.I. Hugo Moser; Project director, Mark L. Batshaw) 1/1/78-12/31/86
Genetic Causes of Mental Retardation
Asymptomatic hyperammonemia-a cause of cortical dysfunction

The purpose of this study was to evaluate neuropsychological function and metabolic abnormalities in adult carriers of ornithine transcarbamylase deficiency.

1KO7NS000342
NIH, NINDS (P.I. Mark L. Batshaw) 3/1/78-28/2/83
Genetics and Metabolism of Urea Cycle Enzymopathies

The goal of this project was to a career development award to study the genetic basis of urea cycle disorders and the use of alternate pathway therapy for treatment.

March of Dimes (P.I. Mark L. Batshaw) 7/1/76/6/30/79
Basil O'Connor Award- Urea Cycle Disorders

The goal of this award was to support a young investigator in studying novel approaches to treating this cause of birth defects using nitrogen free analogues of amino acids.

PENDING:

1T32HD043014 (P.I. Mark L. Batshaw) 5/1/03-4/30/08
NIH, NICHD $185,185
NICHD Institutional Training for Pediatricians (NITP)

The major goal of this project is to help ensure that a diverse and highly trained workforce of pediatricians is available to assume leadership roles in the nations biomedical and behavioral research.

1 U54 MH066417-01A1 7/1/03-6/30/08
NIH, NIMH 1 U54 MH066417-01A1 $1,200,000/yr.
Neurobiological origins and innovative treatment of autism (P.I. Rebecca Landa, Co-P.I. Mark L. Batshaw)

The major goal of this project is to support four projects to study the neurobiological origins of motor planning and communication impairments in autism.

P30 HD40577 (P.I. Mark L. Batshaw) 8/1/03-7/31/06 0%
NIH, NICHD $150,000
Mass Spectrometry Core - Supplement to Mental Retardation and Developmental Disabilities Research Center

The major goal of this project is to support a MS core for proteomics and other state-of-the-art MS methods

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Original Papers

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4. Batshaw M, Brusilow S, and Walser M: Long-term management of a case of carbamyl phosphate synthetase deficiency using keto analogues and hydroxy-analogues of essential amino acids. Pediatrics 1976; 58:227-235.
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common cause of false-positive neonatal screening for tyrosinemia. Md St Med J 1987; 36:429-32.
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Neurobase, La Jolla, CA,CD-ROM 1998.
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Books

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3. Batshaw ML. Your Child Has a Disability: A Complete Sourcebook of Daily and Medical Care, Little Brown & Co., Boston, 1991, 345 pp.
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7. Batshaw ML (ed.). Children with Disabilities, 4th edition. Brookes Publishing Company, Baltimore, 1997, 926 pp.
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9. Batshaw ML (ed). When your child has a disability, revised edition. Paul H. Brookes Publishing Co., Baltimore, 2001, 467 pp.
10. Batshaw ML (ed). Children with disabilities (5th ed). Paul H. Brookes Publishing Co., Baltimore, 2002, 870 pp.

Audiotape

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Trainee History

Trainee	Highest Degree/ Date & Location Where earned	Dates of training	Example of Publication Resulting From Mentorship	Current Position
Bay, Carolyn	MD, Pediatrician University of Rochester School of Medicine,1985	89-92 postdoc	Bay C, Mauk J, Radcliffe J, Kaplan P. Mild Brachmann-deLange syndome: Delineation of the clinical phenotype and characteristic behaviors in a six year old by. Am J Med Genet 1993; 47:965-68.	Asst. Prof. Pediatrics. University of Pittsburgh
Blum, Nathan	MD, Pediatrician Johns Hopkins School of Medicine, 1988	91-94 postdoc	Blum NJ, Mercugliano M. Attention-Deficit/Hyperactivity Disorder. In Children with Disabilities, 4th ed. Batshaw ML (ed). Baltimore. Paul H. Brookes, 1997. p449-470	Asst. Prof. Pediatrics Univ. of Pa. School of Med.
Mars, Audrey	MD Pediatrician Sackler School of Medicine 1986	93-96 postdoc	Mars AE, Mauk JE, Dowrick PW. Symptoms of pervasive developmental disorders as observed in prediagnostic home videos of infants and toddlers. J Pediatr. 1998 Mar;132(3 Pt 1):500-4.	Asst. Professor, Robert Wood Johnson School of Med.
Meyer, Gretchen	MD Pediatrician St. Louis University 1988	94-97 postdoc	Meyer GA. Batshaw ML. Fragile X syndrome. In Batshaw ML (ed). Children with disabilities (5th ed). Paul H. Brookes Publishing Co., Baltimore, 2002, in press.	US Navy: Asst Professor of Pediatrics—Eastern Virginia School of Medicine, Norfolk VA
Glanzman, Marianne Mercugliano	MD Pediatrician University of PA School of Medicine 1983	88-90 postdoc	Mercugliano, M., Hymen, S.L., Batshaw, M.L. Behavioral Deficits in Rats with Minimal Cortical Hypoplasia Induced by Methylazoxymethanol. Pediatrics 1990. 85:S432.	Asst. Prof. Pediatrics. Univ. of Pa School of Medicine
Parrish, Beth	MD Pediatrician	90-93 postdoc	Chen CY, Zimmerman RA, Faro S, Parrish B, Wang Z, Bilaniuk LT, Chou TY. MR of the cerebral operculum: abnormal opercular formation in infants and children. AJNR Am J Neuroradiol. 1996 Aug;17(7):1303-11.	Asst. Prof. Pediatrics, MCH, Hahnemann. Sch. of Med.
Wang, Paul	MD, PhD Pediatrician Yale University 1986	95-96 postdoc	Moss EM, Batshaw ML, Solot CB, Gerdes M, McDonald-McGinn DM, Driscoll DA, Emanuel BS, Zackai EH, Wang PP. Psychoeducational profile of the 22q11.2 microdeletion: A complex pattern. J Pediatr. 1999 Feb;134(2):193-8.	Asst. Professor Pediatrics, U of Pennsylvania School of Medicine
Wray, John	MD Pediatrician University of Western Australia, 1983	96-99 postdoc	Wray JA, Yoon JH, Vollmer T, Mauk J. Pilot study of the behavioral effects of flumazenil in two children with autism. J Autism Dev Disord. 2000 Dec;30(6):619-20.	Princess Maragaret Hospital, Perth, Australia
Robinson, Michael	PhD University of Minnesota 1985	86-88 postdoc	Robinson M.B., Hopkins K., Batshaw M.L., et al. Evidence of excitotoxicity in the brain of the ornithine carbamoyltransferase deficient sparse fur mouse. Dev. Brain Res. 90 (1995) 35-44.	Associate Professor of Pediatrics and Pharmacology, University of Pennsylvania

Trainee	Highest Degree/ Date & Location Where earned	Dates of training	Example of Publication Resulting From Mentorship	Current Position
Anegawa, N.	MD, Univ California, San Francisco, 1998	86-90 predoc	Robinson MB, Heyes MP, Anegawa NJ, Gorry E, Djali S, Mellits ED, Batshaw ML. Quinolinate in brain and cerebrospinal fluid in rat models of congenital hyperammonemia. Pediatr Res. 1992 Oct;32(4):483-8.	Researchet, Neurology UCSF
Gorry, Eileen	BA Yale University 1988	89-90 predoc	Robinson MB, Anegawa NJ, Gorry E, Qureshi IA, Coyle JT, Lucki I, Batshaw ML. Brain serotonin2 and serotoninIA receptors are altered in the congenitally hyperammonemic sparse fur mouse. J Neurochem. 1992 Mar;58(3):1016-22.	Student, Columbia Univ. School of Med.
McLaughlin, Beth	BA Skidmore College 1990	90-92 predoc	Batshaw ML, Yudkoff M, McLaughlin BA, Gorry E, Anegawa NJ, Smith IA, Hyman SL, Robinson MB. The sparse fur mouse as a model for gene therapy in ornithine carbamoyltransferase deficiency. Gene Ther. 1995 Dec;2(10):743-9.	Instructor, Univ. of Pittsburgh, Neurobiology
Pabin, Carol	DVM, Cornell Univ. expected 2003	96-98 predoc	Ye X, Robinson MB, Pabin C, Quinn T, Jawad A, Wilson JM, Batshaw ML. Adenovirus-mediated in vivo gene transfer rapidly protects ornithine transcarbamylase-deficient mice from an ammonium challenge. Pediatr Res. 1997 Apr;41(4 Pt 1):527-34.	Student, Cornell Univ. Veterinary School
Ye, Xuchai	PhD University of Pennsylvania 1988	95-98 postdoc	Ye, X., M.B. Robinson, M.L. Batshaw, C. Pabin, T. Quinn, and J.M. Wilson. "Adenovirus-mediated in vivo gene transfer rapidly protects ornithine transcarbamylase-deficient mice from an ammonium challenge" Pediatric Research. 41, 527-534, 1997.	Asst. Prof. Peds GW
Jerebtsova, Marina	Ph.D., Petersburg Nuclear Physics Institute, 1994	99-present	M.Jerebtsova, M.Batshaw, X.Ye. Humoral immune response to recombinant adenovirus and adeno-associated virus after in utero administration of viral vectors in mice. Pediatr Res. 2002 Jul;52(1):95-104.	Trainee

Attorney Dkt. No. 61688/152

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re; application of:
Xuchai Ye et al
Serial No. 09/972,956
Filed 10/10/2002
Priority date 11/06/2000
For: Gene Transfer Into Renal Glomerular Cells

GAU 1614
Examiner J. E. Angell

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
Box Non-fee Amendment
Washington, DC 20231

Sir:

I, Kurt D, Newman, M.D., hereby declare that"

I reside at

I have been a surgeon for about 25 years, and presently hold the positions of Professor of Surgery/Pediatrics, Vice Chair of the Department of Surgery, and Medical Director of Clinical Resource Management, all at the Children's National Medical Center, Washington, DC, 20010.

I am familiar with the details of the animal model invented by the captioned inventors for the transfer of virus vector-gene constructs into renal glomerular cells.

In my opinion, the inventive renal infusion procedure over 15-120 minutes is feasible for animal model and human applications, and that it is feasible to cannulate the renal vein during the perfusion so that the viral vector not taken up by the renal glomerular cells will not be distributed elsewhere in the body.

It is also my opinion that, at the time of the invention (year 2000) those of average skills in this field would have considered the inventive animal model construct to be specific, substantial and credible as to utility.

6. I hereby also declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the

knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: January 17, 2003

Kurt D. Newman, M.D.